UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,824	01/06/2006	Katsuaki Kurihashi	TAN-C533	1622

7590 06/26/2009

George A. Loud, Esquire
BACON & THOMAS
Fourth Floor
625 Slaters Lane
Alexandria, VA 22314-1176

EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
06/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,824	KURIHASHI, KATSUAKI	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

In the reply filed 11/20/08, applicant cancelled claims 1-18 and added new claims 19-26. Claims 19-26 are currently pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herrick '684 (US 6,290,684) in view of Herrick '270 (US 5,171,270), and further in view of Clayman et al. (US 2004/0092857). Herrick '684 teaches a punctal plug comprising a shaft, a tip portion (190, 212; see Figure 9), a disc-shaped brim 244 attached to the shaft opposite the tip. A protuberance 208 is attached to the tip portion such that the plug is capable of sealing the punctum opening of the eye. Herrick '684 teaches the device substantially as claimed, but does not specifically teach that the punctum plug comprises a loop of thread attached to the plug for pulling out the plug from the punctum opening.

Herrick '270 teaches a canalicular implant for insertion into the punctum of an eye, said implant comprising a pointed tip and a flared, flexible brim. The implant comprises a thread-like member 44 for removing the implant from the eye. Herrick '270

teaches that the application of a pulling force to the implant by means of a thread allows an implant to be easily removed through the punctum of the eye, thereby preventing the need for more invasive means for removing a punctum-canaliculus plug. The use of thread-like members to remove an implanted plug from a patient's punctum is thereby established in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the punctum plug of Herrick '684 with a thread attached to the brim of the implant, as taught by Herrick '270, in order to provide a well known means for removing the implant from the body.

Herrick '270, however, does not teach that the thread-like member comprises a *loop* of thread that passes through the implant in a manner such that the thread terminates at two free ends extending from the plug.

Clayman et al. (hereafter Clayman) teaches a ureteral stent that extends between a patient's ureter and bladder for assisting movement of urine through the body. The stent is inserted into the body through the urethra. Clayman also teaches an extraction thread that is looped through a portion of the stent and is long enough to extend out of the urethra, in order to permit ready removal of the stent by pulling (see [0049], Figure 5A, and Figure 8A). Specifically, Clayman teaches that the extraction thread may be either a single thread tethered to the stent or two threads disposed in a loop. Therefore, because these two extraction methods were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the single extraction thread of Herrick '270 for the looped extraction thread of

Clayman, because doing so would have been an obvious equivalent attachment method to one of ordinary skill in the art.

3. Regarding Claims 21-23, Herrick '684 teaches an implant that is configured to be inserted into the punctum of the eye to prevent fluid flow therethrough, but does not specifically teach the claimed dimensions of the brim. However, mere changes in size or proportion do not constitute patentable improvements in the art when new and unexpected results are not realized (see MPEP § 2144.04. IV. A.). In this case, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the size of the implant and brim in order to meet the needs of a specific patient or application.

4. Regarding Claim 26, Herrick'684, Herrick '270, and Clayman reasonably suggest the device substantially as claimed, but do not specifically teach the claimed diameter of the thread. However, mere changes in size or proportion do not constitute patentable improvements in the art when new and unexpected results are not realized (see MPEP § 2144.04. IV. A.). In this case, it is obvious that small threads should be used in order to reduce the volume of material that must be inserted into the patient's body. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to reduce the diameter of the thread, because doing so would reduce the overall volume and bulk of the implant being inserted into the patient's punctum. Reducing the diameter of the thread does not provide a new and unexpected result.

Response to Arguments

Applicant's arguments with respect to claims 19-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
15 June 2009